## REMARKS

### I. Status of the Application

Claims 1-17 are presently pending in the application. Claims 1, 9 and 10 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. Claims 1-17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., U.S. Patent No. 5,702,716, or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Dunn et al. Applicants respectfully request reconsideration of the pending claims in view of the following remarks.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claims 1, 2, 9 and 10 have been amended to recite that the implant has a porous surface and a substantially nonporous core. Support for a porous surface can be found in the specification at least at paragraph [0025], where Applicants teach that pores are created on the surface of the implant. Support for a substantially nonporous core can be found at examples 1, 3 and 4 where Applicants teach immersion of an implant in plasticizer for 30 or 40 seconds. Applicants have determined that such treatment results in an implant having a porous surface [0025] and a nonporous core (See tab C of Applicants' Response to Final Office Action mailed December 15, 2005). The amendments presented herein add no new matter and do not raise new issues requiring further search. Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

### II. Claims 1, 9 and 10 Are Enabled

At page 2 of the instant Office Action, claims 1, 9 and 10 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner is of

the opinion that the specification, while being enabling for N-methyl-2-pyrrolidone, does not reasonably provide enablement for all plasticizers. The Examiner states that, based on the large amount of known plasticizers and like compounds, it would cause an undue burden on one of ordinary skill in the art to properly make and use the invention. Applicants respectfully traverse this rejection. Applicants respectfully submit that the instant specification provides ample direction and guidance to make and use the claimed invention.

35 U.S.C. §112, first paragraph requires that the specification must enable a person skilled in the art to make and use the claimed invention. However, a specification need not, and should not, disclose what is well known in the art. The invention that one skilled in the art must be enabled to make and use is that defined by the claims of the particular application. The issue of adequate enablement depends on whether one skilled in the art could practice the claimed invention without undue experimentation. Enablement is not precluded by the necessity of some experimentation such as routine screening, ***even if it is extensive routine screening***. Also, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (MPEP 2164.01) if the level of skill in the art is high or if all of the methods needed to practice the claimed invention are well known. *In re Wands*, 8 U.S.P.Q. 2d 1400, 1406 (Fed. Cir. 1988).

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. (Citations omitted). The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 U.S.P.Q. 2d at 1404.

The Examiner is of the opinion that the specification directs one of ordinary skill in the art only toward N-methyl-2-pyrrolidone and makes no mention of other plasticizers fitting the

limitations of the claim or being useful in the invention. The Examiner states that a skilled artisan would have to use trial and error with every known plasticizer in order to find one that exited upon contact with tissue fluids. The Examiner concludes that, based on the large amount of known plasticizers and like compounds, it would cause an undue burden on one of ordinary skill in the art to properly make and use the invention. Applicants respectfully disagree.

Applicants provide ample teachings for identifying additional species of plasticizers using, what in this technology can only be described as, routine testing. Nothing more should be necessary to enable the claimed methods. Determining whether a plasticizer can be used to produce an implant that is flexible prior to insertion into an organ system, and in which the plasticizer exits from the implant after coming into contact with tissue fluids such that the bending resistance of the implant after insertion into an organ system is lower than it was prior to implantation would involve only ***routine screening***, particularly given the high level of skill in the art of implants. Further, determining whether a plasticizer is biocompatible would be routine, as many biocompatible plasticizers have been described in the art, and many plasticizer reference books are commercially available. Indeed, the Examiner admits, at page 2 of the instant Office Action, that the level of ***predictability*** in the art is ***high***, since the ***properties of*** solvents and ***plasticizers are well known in the art***, and that the ***level of ordinary skill in the art is high***. A variety of plasticizers known in the art would be suitable for use with the claimed invention such as, for example, alkyl- or cycloalkyl-substituted pyrrolidones such as NMP, 1-ethyl-2-pyrrolidone (NEP), 2-pyrrolidone (PB), and 1-cyclohexyl-2-pyrrolidone (CP); dimethylsulfoxide (DMSO); glycofurol; triacetin; ethyl benzoate; and benzyl benzoate.

Applicants respectfully submit that the specification teaches a model whereby a water bath treatment represents an organ system which can be used for such routine screening.

Specifically, Applicants teach that sample implants may be treated with a plasticizer, for example, by immersing the implant into a solution containing plasticizer (page 9, paragraph [0030]). The implant may the be submerged in a water bath of 37°C for 24 hours (page 9, paragraph [0031]). Flexibility may then be assayed, e.g., by querying tensile modulus and yield strength (paragraphs [0032] and [0033]). Applicants further teach that instead of water, phosphate buffer may be used (paragraph [0047]). Thus, Applicants provide a system that would easily allow one of skill in the art to screen suitable plasticizers using routine methods. Further, given that the properties of plasticizers are well known in the art and level of skill in the art is high, one of ordinary skill in the art in view of the specification would easily recognize which plasticizers would be suitable for use in the claimed invention, even though the number of suitable plasticizers may be extensive. Applicants are entitled to claim the invention broadly if screening is extensive and not unduly burdensome. Accordingly, based on these teachings and since the only basis for rejecting claims as lacking enablement is the number of possible plasticizers, one of skill in the art could easily make and use the claimed implants.

For at least these reasons, Applicants' specification, coupled with the level of skill in the art, enables a person of skill in the art to make and/or use the claimed invention. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 9 and 10 under 35 U.S.C. § 112, first paragraph.

## II. Claims 1-17 Are Novel and Nonobvious over Dunn et al.

At page 3 of the instant Office Action, claims 1-17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., U.S. Patent No. 5,702,716, or under 35 U.S.C. §103(a) as being obvious over Dunn et al. The Examiner is of the opinion that Dunn et al.

teaches a solid biodegradable implant comprising biodegradable thermoplastic polymers such as polylactides, a plasticizer such as N-methyl-2-pyrrolidone, and growth factors for promoting tissue growth such as fibronectin and human growth factor. The Examiner states: that the implant is formed externally, where the plasticizer substantially exits the implant matrix upon exposure to water in a biological environment; that upon exiting, the matrix will stiffen and form the polymer system having the bioactive agent material within the solid polymer matrix; that the implant is porous; and that the examples teach a process of making implants comprising selecting a biodegradable polymer, adding a plasticizer, and forming an implant. Applicants respectfully traverse these rejections based on the amended claims now presented.

The pending claims are directed in part to a biodegradable implant and a method for manufacturing a biodegradable implant, wherein the implant has a porous surface and a substantially nonporous core. The unique morphology of the claimed implants renders them easy to shape, yet allows sufficient rigidity to support tissues in a desired manner upon implantation (paragraph [0025]). Applicants have already provided evidence of the unique structure of the claimed implant compared to that of Dunn. The Examiner has criticized the photographic evidence as being blurry, however, Applicants respectfully submit that the submitted photographic evidence is very clear, and certainly clear enough to distinguish porous outer portions from a nonporous core. Perhaps, the photograph did not reproduce well during the USPTO scanning process. In that event, Applicants are more than willing to provide the Examiner with an additional photograph should the Examiner desire.

Dunn et al. fails to teach or suggest a polymer having a substantially nonporous core, as claimed by Applicants. In fact, Dunn et al. teaches away from the claimed invention, as this reference teaches that a ***critical feature*** of their invention is a ***porous core***. Dunn et al. is

directed to a polymer system having "a core with large pores of diameters from about 10 to 500 microns and a relatively nonporous skin" (column 2, lines 15 and 60-64). Dunn et al. is concerned with *in situ* controlled release of bioactive material from a polymer system (column 3, lines 33-35). Dunn et al. teaches that core porosity is critical feature necessary for proper functioning of the claimed invention: "The more or less simultaneous diffusion and coagulation produce the microporous structure of the matrix that in part is believed to be a factor in the establishment of the desired control of rate and extent of release" (column 2, lines 56-64). Further, Dunn et al. teaches that, in a preferred embodiment, the skin of their polymers is relatively non-porous (column 2, lines 59-62). Therefore, one of skill in the art, based on the teachings of Dunn et al., would fail to arrive at the claimed invention having a non-porous core and a porous surface.

Thus, Dunn et al. fails to teach or suggest Applicants' claimed invention. Accordingly, Applicants request that the rejections of claims 1-17 under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) be reconsidered and withdrawn.

## III. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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